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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847
2292 7590 08/07/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
08/07/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/584,192

**Applicant(s)**

ONIKI ET AL.

**Examiner**

DARRYL C. SUTTON

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)  
Paper No(s)/Mail Date 6/23/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., In re Gostelli, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus.

As outlined in Univ. of Cal. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), a description of a genus can comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under Section

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112, Para. 1, by showing the enablement of a representative number of species within the genus. Mere indistinct terms (here the term "water-insoluble material"), however, may not suffice to meet the written description requirement.

The instant specification lists approximately 17 specific "water-insoluble material[s]". That listing of 17 species is far narrower in scope than the broad genus "water-insoluble material", and claim 9 fails to recite any structural features common to the members of that genus which would constitute a substantial portion of the same. Accordingly, the term "water-insoluble material" as used currently by instant claim 9 is deemed so indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Januszewski et al. (U.S. 4,159,319).

Januszewski et al. teach a stable anhydrous dentrifice which is comprised of an abrasive, a hydroxypropylcellulose gelling agent and a propylene glycol as essential ingredients (Abstract). The present invention consists of anhydrous

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synthetic zeolite abrasive in amounts of about 20 to 50% by weight, about 0.1 to 5% by weight of at least one flavoring agent, and about 20 to 75% of an anhydrous liquid vehicle consisting essentially of propylene glycol gelled with hydroxypropylcellulose (column 2, lines 30, 34-44). The synthetic zeolites possess acceptable abrasivity for effective cleaning and polishing of teeth (column 3, 46-50). The liquids in the dentrifice will comprise chiefly propylene glycol in an amount by weight of preferably 35 to 60% (column 5, lines 20-30). Preferably about 1 to 5% of hydroxypropylcellulose gelling agent need be used; an amount which is sufficient to form an extrudable, shape retaining product which can be squeezed from a tube onto a toothbrush and will substantially maintain its shape thereon, i.e. toothpaste or tooth gel (column 8, 30-32). In some cases flavorful solvents may be employed. Such flavorings may be solidified by being mixed with a particulate carrier such as a higher fatty acid (column 8, 57-63). Higher fatty acids include myristic acid, oleic acid, linoleic acid, and linolenic acid.<sup>1</sup> It is preferred to use from about 0.05 to 5% by weight of a surface-active material, i.e. surfactant, in the instant oral preparations (column 11, lines 7-10). Januszewski et al. teach a composition comprised of propylene glycol, Klucel GF, i.e. hydroxypropylcellulose, and flavoring (column 14, lines 50-61). The prior art anticipates the instant invention insofar as it discloses a nonaqueous composition comprised of a tooth whitening agent, propylene glycol; higher fatty acids; and a gelling agent, hydroxypropylcellulose, said composition being substantially free of water and peroxide. The compounds of the prior art

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<sup>1</sup> Hirschmann et al., Nomenclature of Lipids, 1976, Appendix A.

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are those disclosed in the instant invention and, therefore, would inherently possess the disclosed limitations of relative permittivity, vapor pressure, solubility, and precipitation characteristics of claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Januszewski et al. (U.S. 4,159,316) as applied to claims 1, 2 and 5 above.

Januszewski et al. are discussed above.

Januszewski et al. does not teach a specific embodiment comprised of hydroxypropylcellulose, propylene glycol, and flavorful solvents which are mixed with higher fatty acids, nor a composition of claim 1 further comprised of a surfactant.

It is prima facie obvious to select a compound based on its suitability for its intended purpose. See MPEP 2144.07. Therefore, it would have been obvious to use the flavorful solvents mixed with either myristic, oleic, linoleic or linolenic acids of Januszewski et al. in the composition. It would have also been obvious to use a surfactant of Januszewski et al. in the composition.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to determine the optimum or workable ranges. Therefore it would have been obvious to determine the optimum or workable ranges of higher fatty acids though routine experimentation.

2. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Januszewski et al. as applied to claims 1, 2 and 5 above, and further in view of Ibsen et al (U.S. Patent Pub. 2002/0006386).

Januszewski et al. is discussed above.

Januszewski et al. does not teach a tool for application of the dentrifice which is detachably fitted to teeth.

Ibsen et al. teach an anhydrous dentrifice, i.e. toothpaste, brushing gel, etc., comprised polyols and gelling agent; preferred organic polyols include

propylene glycol (Abstract, paragraph [0030]). Dentrifices are used to clean, bleach, whiten, and otherwise treat teeth and gums. Generally the active ingredients of a dentrifice are contained within a carrier (paragraph [0002]). The carrier is either a paste, i.e. toothpaste, or a gel. Each is dispensed onto a brushing device or onto a tray, stint, or mouthguard, i.e. mouthpiece. The line between gels and pastes is not always clear. Sometimes dentrifices that are opaque and or contain one or more abrasive fillers are labeled pastes, even if they exhibit gel-like properties (paragraph [0003]).

Ibsen et al. does not teach the specific anhydrous, i.e. nonaqueous, compositions of Januszewski et al.

It is generally prima facie obvious to select a compound/composition based on its suitability for its intended use. Therefore, it would have been obvious to use a tray or mouthguard to deliver the compositions of the primary reference because they are disclosed as suitable for delivering these types of compositions, as supported by Ibsen et al.

All claims are rejected.

### ***Conclusion***



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612